

### **Remarks**

This communication is responsive to the Office action mailed May 21, 2007, in which claims 1-11, 13-21 and 28-32 were pending, with claim being 32 allowed, claims 1-10, 13-21 and 28-31 rejected, and claim 11 as allowable but objected to as being dependent on a rejected base claim.

In the present response, no claims are amended, added, or cancelled; therefore, claims 1-11, 13-21 and 28-32 remain pending in the application.

Applicants address the rejections set forth in the present Office action. According to the following remarks, Applicants respectfully submit that the pending claims are distinguished over the prior art, and are in condition for allowance.

### **35 U.S.C. § 102**

The Office action rejected claims 1-10, 13-21 and 28-31 under 35 U.S.C. §102, as being anticipated by Chudzik *et al.* (7,094,418 B2; herein "Chudzik").

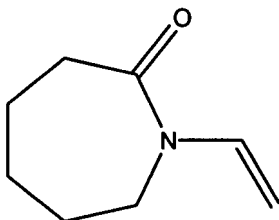
Applicants respectfully traverse the rejection, as Chudzik does not teach all the features recited in the pending claims. In the least, Chudzik does not teach a biocompatible functional group on the polymerization accelerator, in accordance with the claims.

The Office action refers to the teaching of Chudzik in column 11, line 14, regarding a cross-linkable macromer and an accelerator, which can be N-vinyl caprolactam. The N-vinyl caprolactam contains a carbonyl group, and the Office action asserts this can be the biocompatible functional group recited in the pending claims.

Applicants respectfully disagree. The presence of the carbonyl group on N-vinyl caprolactam does not specifically provide a biocompatible group to the N-vinyl caprolactam according the present invention.

Applicants refer to the structure of N-vinyl caprolactam (below) and the teaching on pages 12 and 13 of the present application.

N-vinyl caprolactam (Compound I)

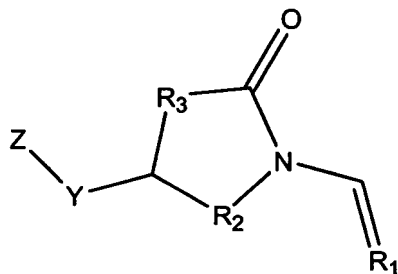


What is missing from the N-vinyl caprolactam of Chudzik is the biocompatible functional group, which (according to some embodiments of the present invention) can be attached to a non-carbonyl carbon on the caprolactam ring.

The present application illustrates the difference between the polymerization accelerators having a biocompatible functional group (as claimed) and the N-vinyl caprolactam of Chudzik.

Page 12, line 17, to page 13, line 25, illustrates this difference.

N-vinyl caprolactam of Chudzik is compared to, and distinguished from, the biocompatible polymerization accelerator compounds of Formula V of the invention (polymerization accelerators having a biocompatible functional group and an N-vinyl amide, wherein the N-vinyl nitrogen is part of a ring):

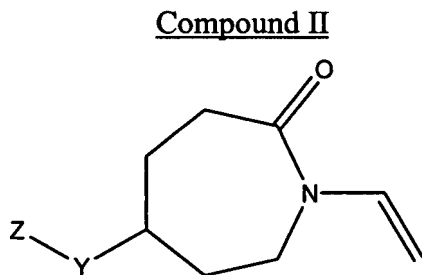


(Formula V);

wherein  $R_1$  is  $\text{CH}_2$ ;  $R_2$  is a covalent bond, 1-4 carbon, oxygen, nitrogen, or sulphur, or combinations thereof;  $R_3$  is a covalent bond, 1-4 carbon, nitrogen, or combinations thereof, with the provision that  $R_2$  and  $R_3$  are not both covalent bonds; optionally  $R_2$  includes a carbonyl carbon;  $Z$  is a functional group that confers biocompatibility and is selected from  $\text{PO}_3^-$ ,  $\text{SO}_3^-$ ,  $\text{COO}^-$ ,  $\text{OH}$ , albumin binding moieties, phospholipid moieties, and the like;  $Y$  is a covalent bond ( $Y_0$ ) or

a spacer ( $Y_1$ ) between the ring structure and group Z, wherein  $Y_1$  is 1-4 carbon alkyl, 1-4 carbon alkoxy, oxygen, nitrogen, or combinations thereof.

(For example, according to Formula V, when both  $R_2$  and  $R_3$  have 2 carbon atoms (e.g.,  $-C_2H_4-$ ), Formula V provides a particular polymerization accelerator of the present invention having the structure:



By comparison (Compound I vs. Compound II) it can be seen that the N-vinyl caprolactam of Chudzik (above) is missing at least group Z (the biocompatible functional group).

Furthermore, the specification makes it clear that N-vinyl caprolactam is not a polymerization accelerator comprising a biocompatible functional group and an N-vinyl group as claimed. The specification at page 13, lines 12-25 discusses the *core* ring structure of Formula V (the core ring structure refers to the portion of the molecule without the biocompatible functional group Z and optional spacer Y) and states:

*Examples of N-vinyl lactam rings suitable for a core ring structure in the polymerization accelerator include N-vinyl capryllactam (1-vinyl-azonan-2-one), N-vinyl enatholactam (1-vinyl-azocan-2-one), N-vinyl caprolactam (1-vinyl-azepan-2-one), N-vinyl valerolactam (1-vinyl-piperidin-2-one), and N-vinyl butyrolactam (1-vinyl-pyrrolidin-2-one). Examples of cyclic N-vinyl amides suitable for a core ring structure in the polymerization accelerator include N-vinyl succinimide (1-vinyl-pyrrolidine-2,5-dione), N-vinyl glutarimide (1-vinyl-piperidine-2,6-dione), N-vinyl maleimide (1-vinyl-pyrrole-2,5-dione), and N-vinyl phthalimide (2-vinyl-isoindole-1,3-dione). Examples of aza-bicyclo alkanone rings suitable for a core ring structure in the accelerator molecule include, for example, 2-vinyl-2-aza-bicyclo[2.2.1]heptan-3-one and 6-vinyl-6-aza-*

*bicyclo[3.2.1]octan-7-one. According to the structure of the N-vinyl lactam, N-vinyl amide, and N-vinyl aza-bicyclo alkanone rings, one or more biocompatible functional groups can be attached to any non-carbonyl carbon on the ring structure(s), optionally spaced from the ring structure(s) by a spacer. (Our emphasis)*

In view of these remarks Applicants assert that Chudzik does not anticipate the pending claims. Withdrawal of the rejection under 35 U.S.C. §102 is respectfully requested.

**35 U.S.C. § 103(a)**

The Office action also rejected claims 1-10, 13-21 and 28-31 under 35 U.S.C. §103(a) as being unpatentable over Hubbell *et al.* (U.S. Pat. No. 5,529,914; herein “Hubbell ‘914”) or Hubbell *et al.* (U.S. Pat. No. 6,258,870 B1; herein “Hubbell ‘870”).

Applicants respectfully traverse the rejection. Hubbell ‘914 or Hubbell ‘870 does not either teach or suggest all the features recited in the present claims.

Applicants note that claim 1 was amended in the response filed February 08, 2007, to recite that the polymerization accelerator comprises an N-vinyl group, which is a preferred feature of the biocompatible polymerization accelerators of the present invention. Applicants’ claim 21 also includes the feature of an N-vinyl group.

Neither Hubbell ‘914 nor Hubbell ‘870 teach a polymerization accelerator comprising a biocompatible functional group and an N-vinyl group as recited in claims 1 or 21.

Hubbell teaches N-vinyl pyrrolidinone, 2-vinyl pyridine, 1-vinyl imidazole, 9-vinyl carbazole, acrylic acid and 2-allyl-2-methyl-1,3-cyclopentane dione (claim 30 of Hubbell ‘870), but none of these have a biocompatible functional group and an N-vinyl group according to the claims. Therefore, Hubbell does not *identically* teach the features of the polymerization accelerator of these claims.

Further, Hubbell does not suggest the modification of an accelerator, such as to provide a biocompatible functional group.

The Office action asserts that the accelerators disclosed by Hubbell *et al.* inherently contain a biocompatible functional group as required by the claims. (The

Office action refers to claims 1, 67, and 68 of Hubbell '914, and claims 1, 30, and 31 of Hubbell '870.) Applicants respectfully disagree. While independent claim 1 of Hubbell '870 recites a "biocompatible polymer," there is nothing in either of the claims of the Hubbell '914 or '870 patents, or the overall teaching of the Hubbell patent that teaches or suggests that biocompatibility is provided by a biocompatible group on the polymerization accelerator.

The Office action states that the polymerization accelerators of Hubbell '914 or Hubbell '870 are inherently capable of binding albumin. Applicants respectfully disagree and assert that this teaching is not found or derivable from Hubbell '914 or Hubbell '870. Hubbell describes albumin in the context of the Examples, where it tests the permeability of PEO gels to albumin (Example 11, Hubbell '870), and in the context of albumin being a suitable macromer for polymerization. However, neither Hubbell '914 nor Hubbell '870 teach albumin binding on account of a polymerization accelerator. Further, neither Hubbell '914 nor Hubbell '870 describe a polymerization accelerator having a long-chain fatty acid group such as oleate, stearate, linoleate, or palmitate.

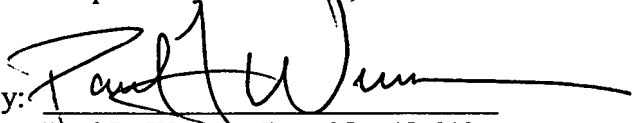
Because Hubbell does not teach or suggest all of the limitations as recited in the pending claims, a rejection based on an asserted *prima facie* case of obviousness is not supported. Withdrawal of the rejection is respectfully requested.

### **CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that all of the claims and the present application are in condition for allowance, which is earnestly solicited. In the event that a phone conference would help resolve any remaining issues in the application, the Examiner is invited to contact the undersigned.

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Respectfully Submitted,

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